Pharmaceutical Sales and Marketing

Compliance Challenges in the New Decade

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Background

On March 4, 2010 Daniel R. Levinson, the Inspector General the Department of Health and Human Services Office of the Inspector General (OIG), testified to the House Appropriations Committee, "We believe that the $4 billion in settlements and court-ordered returns in FY 2009 resulting from OIG fraud investigations is just the tip of the iceberg".[1] Based upon the recent number of record settlement amounts, there is little reason to doubt the validity of this prediction.

The OIG often negotiates compliance obligations with health care providers and other entities as part of the settlement of Federal health care program investigations arising under a variety of civil false claims statutes. A provider or entity consents to these obligations as part of the civil settlement and in exchange for the OIG's agreement not to seek an exclusion of that health care provider or entity from participation in Medicare, Medicaid and other Federal health care programs. While many Corporate Integrity Agreements (CIAs) have common elements, each agreement addresses, in part, the specific facts of the conduct at issue. CIAs often attempt to accommodate and recognize many of the elements of pre-existing voluntary compliance programs.[2]

Utilizing CIAs as a measure, one can see the tremendous increase in activity over the past 10 years. During the most recent 5 years, the OIG has averaged over 80 agreements annually, which is in stark contrast to the years 2001-2005 where the number averaged less than 10 per year (a staggering 735% increase). CIAs are enacted with all types of health care providers – physician practices, hospitals, and long term care entities historically comprise almost three quarters of the agreements. Pharmaceutical manufacturers have made up a mere 5% of the total.[3] However, utilizing a three year average methodology that the OIG employs to examine their fiscal returns, during the years 2007 thru 2009 pharmaceutical manufacturers comprise an astounding 57% of the total dollar amount returned.[4]

Approximately 80% of the OIG's annual funding and workload has been dedicated exclusively to oversight and enforcement activities with respect to health care fraud and abuse in Medicare and Medicaid. The OIG has reported their most recent return on investment for the years 2007-2009 at over

[1] Testimony of Daniel R. Levinson, HHS Inspector General to House Appropriations Committee; March 4, 2010
[2] www.oig.hhs.gov
[3] Analysis of all CIAs posted at www.oig.hhs.gov from 2000-2009
[4] OIG Returns - Pharma percentage represent the total reported OIG Revenues (Department of Health and Human Services, Fiscal Year 2011 Justification of Estimates for Appropriations Committees) divided by the total Pharmaceutical company settlement amounts reported via DOJ press releases during the years 2007-2009.

$17:$1; in other words for every $1 spent the Federal Government expects to receive over $17 in financial recoveries from OIG's Medicare and Medicaid oversight, an increase of over 50% during the past five years. The OIG has forecasted a total average return of $3 billion for the three year period ending October 2010.[5] The OIG has not missed a target in the past 5 years, and appear to be well on their way of attaining this goal as they are almost a third of the way there due to the recent May 2010 settlements with AstraZeneca and Ortho-McNeil-Janssen ($520 million and $81 million respectively).

OIG Funding

It appears that the Federal Government recognizes the financial value returned via the OIG activities outlined above. The Medicare Trust Fund is reported by the Social Security and Medicare Board of Trustees to be exhausted in 2017.[6] This same Trust Fund is the source for funding the Healthcare Fraud and Abuse Control Program (HCFAC). HCFAC, founded via the HIPAA legislation in 1996, is a venture under joint direction of the Attorney General and the Secretary of HHS whereby there is a coordination of enforcement activities with respect to health care fraud and abuse. HCFAC provided 73% of the funding for the OIG in the 2010 fiscal year.[7] President Obama's 2011 budget includes $1.7 billion for HCFAC which includes $561 million in discretionary spending, an 80% increase.[8] In testimony to Congress, OIG Inspector Levinson stated that this funding will allow the OIG to "expand criminal and civil health care fraud investigations and prosecutions, particularly related to emerging fraud schemes in such areas as pharmaceutical services".[9] Additionally, the Patient Protection and Affordability Act has a mandate for an incremental increase of HCFAC funding by $250 million over the next ten years.[10]

[5] Department of Health and Human Services, Fiscal Year 2011 Justification of Estimates for Appropriations Committees
[6] Summary of the 2009 Annual Reports, Social Security and Medicare Boards of Trustees
[7] Testimony of Daniel R. Levinson, HHS Inspector General to House Appropriations Committee March 4, 2010
[8] Testimony of William Corr, J.D., Deputy Secretary on Efforts to Combat Health Care Fraud and Abuse before Committee on Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, United States House of Representatives
[9] Testimony of Daniel R. Levinson, HHS Inspector General to House Appropriations Committee March 4, 2010
[10] Patient Protection and Affordable Care Act, Section (D) 1303

Pharmaceutical Areas of Investigation

In the years 2001-2004, the majority of cases brought against pharmaceutical companies were around the Federal Anti-Kickback law.[11] Most notably, TAP Pharmaceuticals settled for $875 million during this timeframe. However, there appears to be a shift in the type of cases brought forth, as during the years 2005-2009, 84% of cases settled included violations of the Food, Drug and Cosmetic Act and/or the False Claims Act, via off-label promotions.[12] The settlement amounts revolving around off-label promotions have averaged $515 million and historically have demonstrated penalties 2.5 times higher than settlement amounts generated via price reporting or anti-kickback violations.[13] The off-label penalty amounts have been driven upwards most notably by the Eli Lilly settlement in 2009 for $1.4 billion to resolve allegations of off-label promotion of the anti-psychotic Zyprexa, and the $2.3 billion that Pfizer paid later in that same year to resolve criminal and civil liability arising from the illegal promotion of four products including the anti-inflammatory drug Bextra.[14] Off-label cases seem to be more cumbersome to bring forth, however also appear to be more lucrative for the government when it comes to the penalty amounts. Laurie Magid, US Attorney Pennsylvania Eastern District in January 2008 was quoted after the Eli Lilly settlement in 2009, "Off-label marketing cases are not easy to bring. They can take years and involve the review of millions of documents by an alphabet soup of federal agencies, state regulators, and law enforcement officers. But we will keep bringing them until the practice stops."[15]

[11] Analysis of CIAs posted at www.oig.hhs.gov and related DOJ press releases
[12] Analysis of CIAs posted at www.oig.hhs.gov and related DOJ press releases
[13] Analysis of DOJ press releases and DOJ Settlement Agreements
[14] DOJ Press Release "Eli Lilly and Company Agrees to Pay $1.415 Billion to Resolve Allegations of Off-label Promotion of Zyprexa", www.usdoj.gov; DOJ Press Release "Justice Department Announces Largest Health Care Fraud Settlement in History", www.justice.gov
[15] Philadelphia Inquirer January 27, 2009

Off-Label

The FDA does not regulate the practice of medicine and recognizes that physicians may determine that prescribing a drug off label constitutes good care. Although doctors may prescribe drugs off-label, it is not permissible for drug companies to promote drugs for off-label uses.[16] A 2006 study indicated that more than 20% of prescriptions written in the United States were for off-label use.[17]

According to www.cancer.org, off-label drug use is well-documented and very common in certain settings, such as oncology, pediatrics, and HIV/AIDS care. Studies have reported that about half of the chemotherapy used is given for conditions not listed on the FDA-approved drug label. In fact, the National Cancer Institute (NCI) has stated, "Frequently the standard of care for a particular type or stage of cancer involves the off-label use of one or more drugs."[18]

While off-label use may be recognized in the medical community, public sentiment seems to have a contrarian view. In March of this year the Washington Post published an article entitled "When Drug Makers' Profits Outweigh Penalties". Within the text are statements such as, "as large as the penalties are for drug companies caught breaking the off-label law, the fines are tiny compared with the firms' annual revenue." The article continues, "Companies regard the risk of multimillion-dollar penalties as just another cost of doing business. There's an unwritten business plan. They're drivers that knowingly speed. If stopped, they pay the fine, and then they do it again".[19]

Whistleblowers

The vast majority of cases brought forth against pharmaceutical manufacturers are initiated via whistleblowers, or qui tam actions. In our analysis, it appears that over three fourths of the cases settled in the past ten years were brought by qui tam relators' who were employed as sales representatives.[20] It has become common knowledge as to the record settlement amounts made by

[16] GAO Report to the Ranking Member, Committee on Finance, U.S. Senate "FDA's Oversight of the Promotion of Drugs for Off-Label Uses", July 2008.
[17] D.C. Radley, S.N Finkelstein, and R.S. Stafford, "Off-Label Prescribing Among Office-Based Physicians," Archives of Internal Medicine, vol. 166, no. 9 (2006).
[18] www.cancer.org
[19] "When Drug Makers' Profits Outweigh Penalties" David Evans, Bloomberg News, Washington Post March 21, 2010
[20] Analysis of DOJ Settlement Statements

relators' as they can receive anywhere between 15-25% of the financial penalty.[21] Obviously the use of qui tam appears to have become a key enforcement tool used by the DOJ and OIG. According to Senator Charles Grassley (R-Iowa) in October of 2009, "there are over 200 qui tam cases pending on pharmaceutical manufacturers pricing and marketing practices."[22]

It seems that a cottage industry of "professional whistleblowers" has been generated as it relates to the prosecution of pharmaceutical manufacturers for off label violations. The most recent AstraZeneca settlement included a sales representative, James Wetta, as a qui tam relator. It is reported that Mr. Wetta will share some $45 million with the other relator in the case Dr. Stefan Kruszewski. What is particularly interesting is that both relators' have a history with successful qui tam actions. Wetta was a relator in the Eli Lilly case as a sales representative (Eli Lilly settled for $1.4 billion) where he shared in the $100 million awarded to 8 former Lilly employees. Dr. Kruszewski was a relator in the Pfizer case where it is reported that he was awarded $29 million (Pfizer settled for $2.3 billion). Another physician, Dr. Joseph Piacentile, has been a qui tam realtor against Medco Health Solutions (settled for $155 million in 2006), Bristol Myers Squibb (settled for $515 million in 2007), Cephalon (settled for $425 million in 2008), and is currently involved in the claim against Forest Laboratories which is under active investigation[23] (Forest provided a $170,000 pretax expense in connection with ongoing discussions with the DOJ in the fourth quarter of 2009 related to marketing and promotional activities).[24]

Risk Assessment

Pharmaceutical sales and marketing efforts have been, and continue to be scrutinized as it relates to the potential for off label promotions. Manufacturers seem to have established tighter controls in recent years over the development and distribution of promotional materials. However, based upon the number of Department of Justice settlements with pharmaceutical manufacturers for reported off-label violations, companies must proactively assess the risk associated with their direct to healthcare provider activities and subsequently put a program in place to address the identified risks.

[21] False Claims Act 3730 (d) (1)
[22] www.taf.org
[23] Analysis of DOJ Settlement Statements
[24] Forest Laboratories Annual Report 2009

Healthcare compliance risk assessment for pharmaceutical manufacturers' direct sales and marketing activities can be a complex and vague science as there is no distinct and direct guiding principle. Thus, we must examine several sources when analyzing and assessing risk related to healthcare compliance.

The OIG "strongly encourages pharmaceutical manufacturers to develop and implement and refine compliance elements that uniquely address the areas of potential problems, common concern, or high risk."[25] Based upon an analysis of the past 15 DOJ settlements with pharmaceutical companies for violations pertaining to off-label promotions, and subsequent CIAs, it can be concluded that the basis for the vast majority of the violations were related to sales force activity via direct to provider communications.[26] Pharmaceutical sales representatives are unsupervised during the overwhelming majority of their interactions with prescribers.

Peer-to-peer meetings in the form of speaker programs are an effective vehicle for physicians to be educated about a new product, or new developments with an existing product. However, it is important to note that a paid "speaker" is considered an "agent" of the hiring company, and thus must adhere to the same compliance guidelines as a sales representative of the company. Physicians are trained to deliver a company approved product message, however are often asked to provide their medical opinion. Based upon peer-to-peer interactions via questions and answers, speaker programs could present a high risk exposure when it comes to off label promotional compliance.

Risk assessments with regard to direct sales interactions need to be addressed on a periodic basis. The Federal Sentencing Guidelines Manual offers direction and guidance such as, "an organization shall assess periodically the risk that criminal conduct will occur, including assessing the following:

- The likelihood that certain criminal conduct may occur because of the nature of the organization's business.
- If, because of the nature of an organization's business, there is a substantial risk that certain types of criminal conduct may occur, the organization shall take reasonable steps to prevent and detect that type of criminal conduct. …"

[25] OIG Compliance Program Guidance for Pharmaceutical Manufacturers FR Doc. 03-10934

[26] Corporate Integrity Agreements reviewed are: Pfizer Inc. (2004), Serono Holdings, Inc. (2005), Schering-Plough Corporation (2006), Intermune Inc. (2006), Medicis Pharmaceutical Corporation (2007), Jazz Pharmaceuticals, Inc. (2007), Purdue Pharma L.P. (2007), Bristol-Myers Squibb Company (2007), Cell Therapeutics, Inc. (2007), Otsuka America Pharmaceutical, Inc. (2008), Cephalon, Inc. (2008), Eli Lilly and Company (2009), Pfizer, Inc. (2009), AstaZeneca Pharmaceuticals L.P. (2010), Ortho-McNeil-Janssen Pharmaceuticals, Inc. (2010)

- An organization that, due to the nature of its business, employs sales personnel who have flexibility to represent the material characteristics of a product shall establish standards and procedures designed to prevent and detect fraud.[27]

In 2002, the Federal Sentencing Commission established an Ad Hoc Advisory Group to "examine the criteria for an effective program to ensure an organization's compliance with the law". Within this report are several helpful hints as it relates to assessing risk. First, the group offers that "risk assessments need to be made at all stages of the development, testing, and implementation of a compliance program…In short, risk assessment is not a one-time, check-the-box task…"[28] Thus, based upon the changing landscape of the pharmaceutical market, it appears that risk assessments need to be performed with a degree of frequency such as annually.

Former Deputy Attorney General Larry Thompson issued a memorandum in 2003 directed to the United States Attorneys outlining the steps necessary for prosecuting business organizations. Within this memo, commonly referred to as the "Thompson Memo", there are some clear directions related to risk assessments and compliance programs for organization. "An appellant could not gain exculpation by issuing general instructions without undertaking to enforce those instructions by means commensurate with the obvious risks. Prosecutors should therefore attempt to determine whether a corporation's compliance program is merely a "paper program" or whether it was designed and implemented in an effective manner."[29] The memo continues, "Compliance programs should be designed to detect the particular types of misconduct most likely to occur in a particular corporation's line of business."[30] Again, one can conclude that a risk assessment needs to be performed periodically, but also the execution of a program to address the risks identified needs to have documentable evidence of execution. The Federal Sentencing Guidelines Manual adds, "The organization shall take reasonable steps to ensure that the organization's compliance and ethics program is followed, including monitoring and auditing to detect criminal conduct; to evaluate periodically the effectiveness of the organization's compliance and ethics program."[31]

[27] Federal Sentencing Guidelines Manual 8b2.1

[28] Report of the Ad Hoc Advisory Group on the Organizational Sentencing Guidelines October 7, 2003

[29] Title 9, Chapter 9-28.000 "Principles of Federal Prosecution of Business Organizations" Memorandum from Larry D. Thompson, Deputy Attorney General , January 20, 2003

[30] Title 9, Chapter 9-28.000 "Principles of Federal Prosecution of Business Organizations" Memorandum from Larry D. Thompson, Deputy Attorney General , January 20, 2003

[31] Federal Sentencing Guidelines Manual 8b2.1

In summary, each organization should identify the "criminal conduct" that might occur considering the nature of the organization's business, the prior history of the organization, criminal conduct common to the industry, and the legal violations flagged by government regulations. Secondly, assess the nature and seriousness of the legal risks as well as the likelihood that criminal conduct may occur. Lastly, the company needs to prioritize those risks and establish a plan to appropriately address the potential exposures.[32]

Self Reporting

According to the OIG, the failure to prevent or detect the instant offense does not necessarily mean that the program is not generally effective in preventing and detecting criminal conduct.[33] However, there appears to be several incentives for self reporting a violation. According to research performed by the Federal Sentencing Commission, "A number of government programs offer leniency to organizations that self-report violations in a timely manner." Further, current and former US Department of Justice officials have stated to the Advisory Group that the US Department of Justice has declined prosecutions based on the existence of an effective compliance program. An effective compliance program enables organizations to detect violations at an earlier stage than might otherwise occur, and it may thus give them the opportunity to self-report and qualify for lenient treatment under government policies."[34]

Federal Sentencing Guidelines Culpability Score

Violating companies can be prosecuted both criminally and civilly. Often times in order to avoid criminal prosecution, civil fines are negotiated at higher amounts. Of the last 15 DOJ settlements related to off-label violations, 40% (6) of them included a criminal fine due to the negotiated settlement of civil penalties.[35] The criminal fine consists of a base fine, which in the case of a pharmaceutical manufacturer is typically on the highest end of the sliding scale at $72.5 million.[36] From there, a culpability score is

[32] Report of the Ad Hoc Advisory Group on the Organizational Sentencing Guidelines October 7, 2003
[33] OIG Compliance Program Guidance for Pharmaceutical Manufacturers FR Doc. 03-10934
[34] Report of the Ad Hoc Advisory Group on the Organizational Sentencing Guidelines October 7, 2003
[35] Analysis of Government's Memorandum for Entry of Plea and Sentencing with Pfizer, Inc., Serono Holdings, Inc., Schering-Plough Corporation, Jazz Pharmaceuticals, Inc., Purdue Pharma, Inc. and Pfizer, Inc.
[36] Federal Sentencing Guidelines 8C2.4(d)

calculated which will then in turn indicate what the multiplier to the base fine will be. The multiplier can be between 0.05 and 4 times the base fine, which accentuates the importance of the culpability score.

The culpability score is a basic calculation whereby an organization begins with 5 points as a basis. Numbers are added based upon (a) size of the company, (b) the organization's prior history, (c) if there was a violation of a judicial order, and (d) if there was an obstruction of justice. There are two basic areas that allow for a deduction of the culpability score; (1) the existence of an effective compliance program, and (2) self-reporting, cooperating, and accepting full responsibility for the violation.[37] In the 6 criminal fines levied for off-label promotions, no organization received the 3 point reduction for having an effective compliance program. Further, no organization received the 5 point reduction for self reporting. The average culpability score was 8, which in turn led to a multiplying factor range of 1.6 to 3.2.[38] If each of these organizations had received the 3 point reduction for having an effective compliance program, that could have meant savings of $35-$70 million based on the original assumption of a $72.5 million base fine. These same fines could have been reduced if they received the 5 point reductions for self reporting, cooperating, and accepting full responsibility by another $58-$116 million.

Patient Protection and Affordable Care Act (PPACA)

The recently passed health care reform legislation includes several provisions to further enforcement of healthcare fraud and abuse, and potentially increase the challenges faced by pharmaceutical manufacturers. Aside from the average $3 billion annually in incremental tax assessed to branded manufacturers[39], there are several provisions that enhance the ability of the government to investigate potential fraudulent activity. There is now a requirement for CMS to include claims and payment data into an integrated repository, and subsequently grants the Department of Justice access to that data for oversight activities in real time.[40] According to Levinson, "the OIG has developed and leads a data analysis team to identify fraud patterns and trends and strategically target all of our resources."[41] PPACA also loosens the requirements for qui tam relators' to include authorizing the court to try a qui

[37] Federal Sentencing Guidelines 8C2.5
[38] Analysis of Government's Memorandum for Entry of Plea and Sentencing with Pfizer, Inc., Serono Holdings, Inc., Schering-Plough Corporation, Jazz Pharmaceuticals, Inc., Purdue Pharma, Inc. and Pfizer, Inc.
[39] Patient Protection and Affordable Care Act, Section 9008
[40] Patient Protection and Affordable Care Act, Section 6402
[41] Testimony of Daniel R. Levinson, HHS Inspector General to House Appropriations Committee March 4, 2010

tam action that was publicly disclosed and in which the relator is not an original source; this overturns the Supreme Court ruling in March 2010 against such action.[42] Thus, it may now be easier for more individuals to come forward via qui tam lawsuits. The Federal Sentencing Guidelines are also amended in this legislation to increase the penalty amounts up to four-fold amount depending upon the amount of claim in question.[43]

Field Force Monitoring Programs (FFMPs)

The OIG has indicated that monitoring of direct interactions between company sales representatives and health care providers may be an effective compliance enforcement mechanism. According to the OIG Guidelines, "A pharmaceutical manufacturer should establish an effective system for reviewing information about sales force activities, including, if appropriate, random spot checking. It is often effective to have internal or external evaluators who have relevant expertise perform regular compliance reviews."[44] In fact, 10 of the 13 CIAs entered into with pharmaceutical manufacturers since 2006 have included a mandatory independent field force monitoring program.[45] The OIG factors in establishing FFMPs are the existing compliance and detection programs, prior investigations and CIAs, and the size of the company.[46] The details behind these mandated programs have become more rigid over time, mandating independence from sales and marketing departments, and in the case of Pfizer mandating HCC personnel or a "field based attorney" hired or employed by the company.[47] Monitoring of sales force activities appears to have become a focus by the OIG both in their investigations and the corporate integrity agreements. Additionally, speaker program monitoring has been mandated in the latest three CIAs related to off-label promotions.[48] A peer-to-peer meeting in the form of Speaker Programs is an effective vehicle for physicians to be educated about a product. A paid "speaker" is considered an "agent" of the hiring company, and thus must adhere to all of the same compliance guidelines as a sales representative of the company. Thus, speaker programs have been under OIG scrutiny during investigations.

[42] "Justices Limit Qui Tam Cases but New Health Care Law Does Opposite" Marcia Coyle, The National Law Journal March 31, 2010
[43] Patient Protection and Affordable Care Act, Section 6408
[44] OIG Compliance Program Guidance for Pharmaceutical Manufacturers FR Doc. 03-10934
[45] Analysis of CIAs posted at www.oig.hhs.gov
[46] www.oig.hhs.gov
[47] www.oig.hhs.gov
[48] www.oig.hhs.gov

Summary

The mission of the OIG, as mandated by Public Law 95-452 (as amended), is to protect the integrity of Department of Health and Human Services (HHS) programs, as well as the health and welfare of the beneficiaries of those programs, by detecting and preventing waste, fraud, and abuse.[49] It has been clearly demonstrated that substantial dollar amounts have been returned to the Medicare Trust Fund and State Medicaid programs via civil and criminal prosecutorial settlements from pharmaceutical manufacturers. Of the twenty nine companies representing the trade group PHRMA, almost 60% of them are under an active CIA, have an expired CIA, or are under active ongoing investigation.[50]

Pharmaceutical manufacturers need to take proactive voluntary measures to comply with company healthcare compliance policy, and document the execution of those measures. There are several challenges to confront while implementing proactive measures: new financial obligations via the Patient Protection and Affordable Care Act, headcount numbers have declined industry wide and thus people are "doing more with less", and the labor intensive monitoring activities can in turn be a tremendous strain on available resources.

[49] www.oig.hhs.gov
[50] Analysis of PHRMA companies at www.phrma.com; Analysis of CIAs at www.oig.hhs.gov